IN THE UNITED STATES DISTRICT COURT

FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

GRETCHEN S. STUART, M.D.; *et al.*, Plaintiffs, v. JANICE E. HUFF, M.D. *et al.*, Defendants.	Civil Action No. 1:11-cv-804-CCE

DECLARATION OF GREGORY J. BRANNON, M.D., IN SUPPORT OF PROPOSED DEFENDANT INTERVENORS' MOTION FOR INTERVENTION

I, GREGORY J. BRANNON, M.D., declare as follows:

1. I am not a party or related to a party in this action. I am over the age of eighteen and am competent to testify. I am in private practice as an obstetrician and gynecologist in Cary, North Carolina. I am board certified by the American Board of Obstetrics and Gynecology (ABOG) and a fellow in the American College of Obstetrics and Gynecology (ACOG). Since 1993, I have been continuously licensed and have practiced medicine in the State of North Carolina.

2. I obtained my medical degree from the Chicago School of Medicine, North in 1988 and completed my obstetric and gynecological residency at the University of

Southern California Women's Hospital / Los Angeles County Medical Center. I am affiliated with Wake Medical Center Cary Hospital in Cary, North Carolina, and have served on various hospital committees including gynecology surgical procedures, Ante/Intrapartum protocols and procedures. I have participated in Christian Mission trips and provided obstetric and gynecological care in the following third world countries: Costa Rica, El Salvador, Panama and Gabon, Africa. A true and correct copy of my *Curriculum Vitae* is attached hereto and incorporated herein by this reference as Exhibit A.

3. I have delivered over 8,000 babies. As an integral part of my medical practice in obstetrics and gynecology, I have counseled and discussed medical options with thousands of women in North Carolina who were pregnant, many of whom were seeking my medical opinion and advice whether to terminate or continue their pregnancies in a broad variety of circumstances. As a consequence of my education, qualifications and years of experience in the medical practice of obstetrics and gynecology, I am familiar with all relevant medical standards of care in this community, particularly the standards of care for the fully informed and voluntary consent that ought to be given and received before performing a surgical or medical abortion and the uses of obstetrical ultrasound technology in the treatment and termination of pregnancy.

4. Although I do not perform elective induced abortions I have evacuated thousands of first trimester and scores of second trimester pregnancies for fetal demise in North Carolina using the same surgical procedures used for elective induced abortions. In addition to delivering babies I perform pelvic surgery which includes hysterectomy,

tubal ligation, ovaries, bladder repair, and pelvic relaxation repair. In all of these procedures I am required by law and the medical ethics of my profession to obtain the informed consent of the patient and, if the patient is a minor, the informed consent of her parent or guardian. I have provided information sufficient to obtain a truly voluntary and fully informed consent from my patients in North Carolina well over 10,000 times.

5. I seek intervention as a defendant-intervenor in this action on my own behalf as a physician, on behalf of the pregnancy support centers where I provide care, and on behalf of my patients. I have read the Complaint filed herein and the recently enacted "WOMAN'S RIGHT TO KNOW ACT" being challenged in that Complaint on the various grounds set forth in this action. (H.B. 854, enacted July 28, 2011, N.C. SESSION LAW 2011-405, the "Act"). I am knowledgeable concerning the facts set forth therein, and if called to testify would do so, as follows.

Informed Consent in Obstetrics & Gynecology

6. In addition to any patient history, physical examination or biochemical testing a physician may have performed or taken, absent an emergency situation as defined in the Act, it is the common practice and medical standard of care in North Carolina for the physician to also perform (or supervise the performance) of an ultrasound examination to date and verify an intrauterine pregnancy (or embryonic or fetal demise) and the gestational age of the human embryo or fetus.

7. It is also the common practice and medical standard of care in North Carolina for doctors providing obstetrical and gynecological care, including the termination of pregnancy, to be trained to supervise, perform and interpret obstetric

ultrasonography. Given this common practice and standard of care, it is common for such doctors to work in conjunction with a medical technician who works under the doctor's medical supervision, and whose competency to perform and interpret obstetric ultrasonography has been certified as set forth in the Act. In the absence of such competent assistance it is the common practice and standard of care in North Carolina for most doctors to perform, interpret and explain the results of the ultrasound to the mother before obtaining her informed consent to terminate the pregnancy.

8. When giving an ultrasound, a doctor or trained technician must decide between using a vaginal or abdominal transducer and also must choose the transducer frequency. The standard of care in this regard is to select that technique which will produce the clearest image and thus best depict the gestational age, presence of limbs and cardiac activity to determine fetal health or demise, and existence of an intrauterine or ectopic pregnancy.

9. Informed consent of a patient concerning the removal of an organ or tissue cannot be obtained unless the patient understands the function of that tissue and what information is available for diagnosing the condition of that tissue. For example, when both ovaries are surgically removed, this effectively places the woman in menopause. It must therefore be explained to her the hormonal function of the ovaries that are being removing. This is in addition to the risk of the surgery itself. In the performance of a tubal ligation (popularly known as "tying the tubes") Medicaid law requires a 30 day waiting period and detailed information to be provided as to the consequences for the future infertility of the patient.

10. Likewise, in discussing a pregnant woman's choice to deliver or terminate her pregnancy, it is impossible to obtain a truly voluntary and fully informed consent to an abortion without discussing with the nature of the tissue is to be removed. In the case of an abortion, the tissue to be removed is a separate, unique living human being who is genetically different from the mother. All obstetrician and gynecologists know this biological fact. This information is not commonly understood by all women, however, particularly in the first trimester of pregnancy, and is directly relevant to their decision-making. So the provisions of the Act requiring display of the ultrasound image, factual description of what the ultrasound depicts, and medical description of the ultrasound image are fundamental to fully informing a woman about the human fetus already in existence and her decision whether or not to continue or terminate the pregnancy.

11. The Act does nothing more than to legally require what most obstetricians and gynecologists in North Carolina commonly do and what our medical ethics already counsel and advise. Far from impairing the physician-patient relationship, the Act simply conforms the law to the existing standards of care for diagnosing the condition of pregnancy and obtaining the patient's knowing and voluntary consent before a pregnancy is surgically or medically terminated. The free flow of information required by the Act does not impair the physician-patient relationship, but strengthens it. The patient is not burdened but better informed and empowered and protected by gaining this knowledge.

12. It is in the best interests of North Carolina women to assure that all pregnancies are properly diagnosed and never terminated without a full disclosure of the relevant medical facts followed by a fully informed and voluntary consent. In the

instructive words of the ACOG Committee's Opinion 363 on Patient Testing, attached hereto and incorporated herein as Exhibit B: "in addition to establishing a diagnosis," which is precisely what an obstetric ultrasonographic examination establishes, such "testing provides opportunities to educate, inform and advise. The ethical principles of respect for autonomy (patient choice) and beneficence (concern for patient's best interests) should guide the testing, counseling and reporting process. Clear and ample communication fosters trust, facilitates access to services and improves the quality of medical care."

13. Attached as Exhibit C hereto is an ultrasound image of an 8 week 1 day (by Hadlock) (6 weeks-1 days after fertilization) unborn child. It is my expert medical opinion that using a real-time display of this kind of image, a physician or a qualified technician working in conjunction with a physician can simultaneously explain to the mother all of the information required by § 90-21.85 of the Act and that such display and explanation is a vital prerequisite for the fully informed consent that a physician ought to obtain before terminating a pregnancy.

The Important Role of Pregnancy Care Centers

14. The work of pregnancy support centers will be potentially increased by the Act because much of the information that is required by the law to be given 24 hours ahead of time may be given by these centers rather than by the doctor who is to perform the abortion. This requirement will improve the informed consent process without unduly burdening the patient.

15. I am also the Medical Director for Hand of Hope Pregnancy Center (HHPC) which is located in Fuquay Varina, North Carolina and will soon be the Medical Director of Pregnancy Life Care Center headquartered in Raleigh, NC. At HHPC I review the counseling materials provided, check for accuracy, and supervise all medical services provided. HHPC provides sonograms and I am available to review them and interpret them for the clients. I will counsel these women about the sonogram when necessary. The women I see for counseling are often seriously considering abortion. I see them to insure that they are not being coerced in any way and are fully informed before they make the irreversible decision to terminate the life of their offspring.

16. Once I take on the client for counseling, I am accepting the pregnant mother as a patient and I owe to her all of the duties any physician owes to his or her patients. Thus, I have a duty to make accurate and truthful disclosures concerning all of the procedures the pregnant mother is considering, including abortion and childbirth, and the options to both. My obligation is to make proper disclosures, whether I shall perform the procedure for childbirth or not (I do not perform abortions). It is universally understood and accepted within our specialty that the obstetrician/gynecologist has a duty to two separate patients, i.e., the mother and her child. I have a duty of disclosure to both. Disclosures to the child, and about the risks or harms to the child must be made to the pregnant mother and only she can make the decision for the child.

17. Although I do not perform abortions I do let my patients who choose to have an abortion elsewhere know that I will take care of them if complications result after their abortions and will provide routine post care.

18. Except in emergency situations, a fully informed and truly voluntary consent is best obtained well in advance of any operation or procedure. The reason for this is that the patient needs to think about the information, digest it and decide if she has additional questions. After providing initial information patients often come back to me on subsequent days with additional questions that they did not think of the first time we discussed the proposed procedure. It is a common practice in obstetrics and gynecology to give all of the information necessary for fully and voluntary informed consent by all of the following methods: orally, in writing and even by DVDs.

19. Towards this end, a 24 hour waiting period to reflect on the information provided by a physician or qualified professional prior to an abortion is both reasonable and necessary given the pressures most women in my experience feel in this crisis decision-making time. After displaying and describing the ultrasound imaging, the Act requires a 4 hour waiting period. Abortion decision-making is often associated with ambivalence and/or coercion. This limited time period helps ensure a woman's decision is firm, her own, and in her best interests, based on full and complete information. If a woman is being coerced into an abortion and is pressured into proceeding and led to believe that the pregnancy is "nothing more than tissue," her decision is not truly voluntary nor fully informed. If she is ambivalent, more information and clarification of what her pregnancy consists of is likely essential for helping her in her decision-making. Without receiving this dispositive developmental information derived from the ultrasound regarding the gestation of her pregnancy, she may be at risk of proceeding with the abortion and experiencing adverse psychological problems afterwards. Such a

circumstance would be unethical, cruel and injurious to women who have the right to be fully informed. Waiting periods rightly inform patients of the gravity of their decision-making and provide opportunity for reflection and more consultation. In the case of abortion, this decision is unique in medicine with grave and irrevocable consequences, i.e., the demise of her offspring.

20. Plaintiffs argue that the Act's display and disclosures may cause stress for some women upon being provided with the truthful and complete medical information. In my medical opinion that is not a reason to omit the information. The nature and process of informed consent may be difficult and even stressful, but vital for considered decision-making. Any diagnostic imaging shown to a patient has the potential to cause a patient to be concerned or even anxious about her circumstances or diagnosis. To my mind, for the physician to not display nor discuss these images would convey an improper and unethical message of medical paternalism at its worst.

21. In other fields of surgery all material information is provided regardless of whether or not it causes stress. Indeed, respect for patient autonomy demands this. For example, if a woman has a vaginal hysterectomy there is a 1% chance of incidental cystotomy – which is an incidental hole in the bladder. During the process of obtaining the consent for this procedure I discuss this possibility and what would be required to respond to it, including the repair and the long term effects. If a woman stated she did not want to hear about that 1% chance of a cystotomy and refused to listen to the information provided, I could not obtain her fully informed and truly voluntary consent

without a detailed discussion of her reasons for such a refusal and thus, would not be able to operate.

Additional Concerns

22. Some of the declarants in plaintiffs' declarations make a point that childbirth is more dangerous than abortion. Because maternal mortality data suffers from considerable definitional issues, incomplete and inconsistent reporting, lack of comparability between childbirth and abortion, lack of nationwide mandatory reporting, and other factors, any direct comparisons about the deaths from abortion versus childbirth are unreliable at this time. The Act specifically states that the risk of childbirth shall be included in physician disclosures as well.

23. Further, these declarants do not even state what risk they include and from a review of their practice and literature, it appears that they do not include the very significant risks of subsequent preterm birth and extremely low birth weight in future pregnancies. Some doctors who perform abortions apparently do not discuss this as a risk because I understand that some abortion organizations instruct them that it is not a risk required to be disclosed. But this information is not otherwise commonly known, and a reasonable woman who contemplates a future pregnancy is entitled to know it before electing to have an abortion. We routinely discuss risks with much less incidence of occurrence than the overwhelming evidence for statistically significant increased risks after induced abortion for premature labor and extremely low birth weight.

24. Although current medical literature does not prove that abortion causes breast cancer, an increased risk is apparent for women with a history of breast cancer in

their families of origin and who terminate a pregnancy as opposed to those women who have been pregnant and delivered previously or miscarried. The presumed etiology is that early age at full term pregnancy has a protective effect against future breast cancer. In contrast a spontaneous miscarriage does not result in the loss of this protective effect.

25. Mental health complications associated with abortion are also reported in the scientific literature. These include depression, anxiety, substance abuse and suicidal ideation, among others. While causation cannot be definitively established due to multicausality, the research is clear that some women are at greater risk of psychological problems following abortion than others. For example, those who have pre-existing mental health issues, are ambivalent, feel pressured or coerced, lack support of significant others, have had a previous abortion, a second trimester abortion, etc. are at increased risk. Women deserve and have the right to know this information prior to an abortion.

26. Given the current state of medical knowledge, the Act's required disclosures are both reasonable and beneficial, not burdensome, for women considering abortion and making an informed choice. The law requires among other things: "at least 24 hours prior to the abortion, a physician or qualified professional has orally informed the woman, by telephone or in person, the particular medical risks associated with the particular abortion procedure to be employed, including, when medically accurate, the risks of infection, hemorrhage, cervical tear or uterine perforation, danger to subsequent pregnancies, and any psychological effects associated with the abortion."

Personal Impact of This Law on My Practice & My Patients

27. It is my medical opinion that the disclosures required under the Act are of the utmost importance to pregnant mothers. My ob-gyn practice is based upon a solemn responsibility to convey accurate and complete information to my patients so their medical decision-making can be fully informed. If this case is decided adversely to the State and the Statute is declared unconstitutional on the basis that the disclosures are misleading, ideological and inaccurate statements, as plaintiffs seek, I am personally affected in numerous and important ways. I now seek to intervene in this matter so that my own interests, those of my patients, and those of pregnancy support centers where I provide medical services are properly protected, litigated and advanced.

28. I have a legal, professional and moral duty, as well as a personal and professional interest, to provide accurate, truthful and full disclosures to all of my patients. I also have a right to speak freely and accurately with my patients. It is clear to me that I have an important interest in protecting my own rights and interests and the rights and interests of my patients. My rights and interests are inextricably interconnected to theirs. As a physician, I have both the right and responsibility to tell the truth. If plaintiffs were to succeed in this lawsuit and have the Act declared unconstitutional because the Statute required non-truthful and misleading facts or mere ideology, my interests would be seriously and adversely affected. If that were to occur, that would amount to an affirmation that all of the counseling I have provided was false or misleading and thereby subject me to the following adverse outcomes: civil liability; possible disciplinary action by the state medical regulatory authority including potential suspension or revocation of my medical license. This would then force me to alter my

counseling, requiring me to make false and misleading disclosures and compel me to stop giving accurate factual and medical explanations. In short, it would prevent me from speaking freely on what I believe is truthful and accurate information. If I continued to provide what I know is truthful and accurate facts, I would then be immediately subject to all of the sanctions I outlined here, not just for past counseling, but for present and future counseling in my patient care. Because of the order and decision already entered in this case, which states that the plaintiffs have a fair chance of success because the disclosures are inaccurate or ideological compelled speech, as a matter of fact, I am already exposed to all of these sanctions and liabilities and will continue to be exposed. This is an untenable circumstance in which to be placed. Accordingly, I find that only I can properly protect my legal interests and the interests of my patients, and properly adjudicate the common questions of law and fact that my claims and defenses share with claims and defenses being asserted in this case, by intervening in this action as a defendant intervenor.

29. Additionally, my legal rights and other interests, as well as the legal rights and other interests of my pregnant patients will be adversely affected. Those legal rights and interests depend almost entirely upon the truthful, accurate and complete disclosures being given to them in order for them to make fully informed and voluntary pregnancy related decisions. For example, if plaintiffs succeed in this case, civil remedies that both I and my pregnant patients would otherwise enjoy under Section 90-21.87 of the Act would be unavailable "against the person who performed the abortion in knowing or reckless violation of the Act."

30. As a defendant-intervenor I will do nothing to unduly delay or prejudice the adjudication of the original parties' rights in this action.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct. Executed on November 7, 2011.

Gregory J. Brannon, M.D.

EXHIBIT A:

Curriculum Vitae

of

Gregory J. Brannon, M.D.

Gregory Joseph Brannon, MD
108 Trident Ct. Cary, NC 27518
919-210-1874
Greg.brannon@earthlink.net

Personal: Married 24 years to Jody Brannon. Six children ages 5 to 21, five daughters, one son.

EMPLOYMENT

- 1992 Obstetrician & Gynecologist/ North Shore Medical Group, Huntington, NY
- 1993-1995 Obstetrician & Gynecologist/Clinical Assistant Professor UNC Chapel Hill Wake AHEC, Raleigh, NC
- 1994-1997 Gynecologist/Gynecological Pelvic Surgery, NC Correctional Women's Correctional Facility, Raleigh, NC

Private Medical Practice:

- 1993-1996 Gregory J. Brannon Obstetrics and Gynecology, P.A., Cary, NC
- 1997-2009 Brannon & Rogers Obstetrics and Gynecology, P.A., Cary, NC
- 2009-present Brannon Obstetrics and Gynecology, P.A., Cary, NC

EDUCATION

- Bachelor of Science, University of Southern California, Los Angeles, CA, Biological Sciences, 1982
- Doctor of Medicine, Chicago School of Medicine, North Chicago, IL 1988
- Obstetrics and Gynecology Residency, University of Southern California – LA County Women's Hospital – 1988 - 1992

HOSPITAL AFFILIATIONS

1993 to present Wake Med Cary Hospital, Cary NC

- On various committees to assist with the planning and design of the Women's Pavilion and Birthing Center.

- Various other committees including gynecology surgical procedures, Ante/Intrapartum protocols and procedures

MISSION WORK

- 2007 Costa Rica Christian Mission Trip with my child age 17.
- 2007 Gabon, Africa/ Bongolo Hospital Christian Mission Trip, Instructed Surgeons on technique, protocol and procedures. Led daily bible studies.
- 2009 El Salvador Christian Mission Trip with my child age 14.
- 2009 Costa Rica/ Panama Christian Mission Trip with my child age 17.

BUSINESS ASSOCIATIONS

- 2011 Founder and board member of LocalSense, a data technology company

EDUCATIONAL ASSOCIATIONS

- 1994 to present Founding family and Board Member of Cary Christian School, Cary NC
- Member of various committees, including curriculum, finances, and fundraising.

PERSONAL INTERESTS AND TRAVEL

- Bible Study Leader- 12 years
- Interests include American and World History
- Coaching soccer, hockey, golf
- Hobbies include, golf, physical fitness, active life style
- Traveled to China in 2006 and 2008 to adopt two children

- Traveled to China in 2006 and 2008 to adopt two children
- Traveled to Scotland, Ireland and Mexico
- Traveled to many cities within the USA

EXHIBIT B:

ACOG Committee's Opinion 363 on Patient Testing

ACOG COMMITTEE OPINION

Number 363 • April 2007

Patient Testing: Ethical Issues in Selection and Counseling*

Committee on Ethics

ABSTRACT: Recommendations to patients about testing should be based on current medical knowledge, a concern for the patient's best interests, and mutual consultation. In addition to establishing a diagnosis, testing provides opportunities to educate, inform, and advise. The ethical principles of respect for autonomy (patient choice) and beneficence (concern for the patient's best interests) should guide the testing, counseling, and reporting process. Clear and ample communication fosters trust, facilitates access to services, and improves the quality of medical care.

In the practice of medicine, clinical evaluation is enhanced by a broad range of tests. Recommendations to patients about testing should be based on current medical knowledge, a concern for the patient's best interests, and mutual consultation. Patient testing embodies many scientific and human ideals. From an ethical perspective, the most important principles involve a trusting patient–physician relationship emphasizing beneficence (the benefits the patient may derive from testing) and respect for autonomy (an appreciation that patients make choices about their medical care). Issues of nonmaleficence (using tests when the consequences of the test are uncertain) and justice (applying tests to low-risk groups) also may be important (1).

Rapid technologic development and the need to consider legal and sociocultural factors as well as medical knowledge have increased the complexity of the decision-making process. The physician often is in the position of ordering tests—for human immunodeficiency virus (HIV) or genetic markers, for example—that may, unlike a urinalysis or a hemogram, have a profound effect on the patient, her partner, her family, and society in general. This new level of complexity requires the specification of both medical and ethical guidelines for decisions about patient testing. This Committee Opinion provides ethical guidance for decisions about ordering tests, counseling patients, and reporting results.

*Update of "Patient Testing," in *Ethics in Obstetrics and Gynecology*, Second Edition, 2004.

Ordering Tests

- *The physician and the patient have a shared responsibility.* The quality of medical care improves when there is clear communication and mutual understanding between physician and patient. It is the responsibility of the obstetrician–gynecologist to communicate effectively and to develop skills that promote a patient–physician relationship that is characterized by trust and honesty. Similarly, it is the responsibility of the patient to provide accurate information about her lifestyle, health habits, sexual practices, and religious and cultural beliefs when these factors may affect medical judgment. In decisions about testing, physicians should be guided by scientific knowledge. Care must be taken to avoid subjective assumptions based on bias that could affect the appropriateness of testing (2).

The American College of Obstetricians and Gynecologists
Women's Health Care Physicians

- *Testing should be performed primarily for the benefit of the patient.* Testing at the request of third parties—partners, health care providers, members of the patient's extended family, employers, or health insurers—is justifiable only when the patient or her valid proxy understands the potential risks and benefits and gives consent (3). Examples of this type of testing include genetic tests to assist family members with reproductive decisions, HIV tests to fulfill conditions for the purchase of life insurance, and requests for patient testing after the occupational exposure of health care workers.
- *The decision to offer or to withhold a test should not be made solely on the basis of a physician's assumptions about the patient's expected response to test results (4).* Prejudgments about a patient's wishes regarding fetal abnormalities, for example, should not preclude her being offered prenatal testing. The patient should join with the physician in deciding the amount of diagnostic information that is appropriate for making intelligent choices about preventive care and treatment options. The physician is not, however, ethically obligated to perform every test a patient requests, particularly if disease prevalence and risk factors are low, generating a high false-positive risk.
- *The patient must be informed prospectively about policies regarding use of information and legal requirements.* The patient must be told what will be communicated, to whom, and the potential implications of reporting the information. If, for example, a patient is concerned about posting HIV test results in the medical record and who may have access to the results, she may choose instead to use an anonymous testing procedure available through another laboratory. In some situations, reporting of results is mandated by law. Physicians should be familiar with the laws regarding mandatory testing and reporting requirements in their own jurisdictions.
- *The physician and patient should discuss concerns about cost containment and reimbursement.* The mutual goal of physician and patient should be to avoid both undertesting and overtesting. Contemporary focus on the economics of health care has created worries for both physician and patient about access to care, limitations to testing, appropriateness of use, and the impact of financial constraints on quality of care. Testing done with low probability of improving patient diagnosis or testing solely for the sake of professional liability concerns should be avoided. Open communication about cost concerns and perceived benefit is the best way to alleviate suspicion and to promote trust.

Pretest and Posttest Counseling

- *Testing that may have multiple medical or psychosocial consequences requires specific counseling.* The extent of counseling beneficial to each patient will vary depending on the individual and on the implications inherent in the potential test results. With simple tests like urinalysis, it is sufficient to provide information about the nature and purpose of the test and how the results will guide management. Tests that may have multiple medical or psychosocial ramifications require comprehensive explanation of the process, the goals, and the implications (4). Counseling can be appropriate for genetic testing and maternal toxicology assays, for example, because of the potential for psychologic, social, and economic effects. Tests with low positive predictive value, such as cervical cytology and mammography, can generate the need for additional and more extensive testing. Testing for HIV or inherited breast cancer mutations may limit future insurance coverage.
- *In some cases, the potential benefits—including societal benefits—of certain tests may lead some to recommend alternative schemes for counseling and consent in order to maximize the rate of testing.* The U.S. Centers for Disease Control and Prevention, ACOG, and the American Academy of Pediatrics have endorsed an "opt-out" protocol with patient notification for prenatal HIV testing (5–7). The use of patient notification provides women the opportunity to decline testing but eliminates the requirement to obtain specific informed consent.
- *Autonomy of the individual in shared decision making should always be respected.* It is essential in the informed consent process that subsequent election of the patient to forgo a recommended intervention (informed refusal) be carefully documented in the patient's medical record along with the patient's reason for refusal. Both pretest and posttest counseling facilitate women's access to appropriate health care. Pretest counseling includes both medical considerations and issues such as the availability of emotional support while waiting for test results. Posttest counseling offers an opportunity to provide access to resource networks and community-based services.
- *Referral may be needed for comprehensive counseling.* If time constraints or lack of technical expertise make it difficult to offer comprehensive counseling in a particular practice, appropriate options include either 1) referral to a specialized center for both counseling and testing, or 2) referral for counseling only, with return to the original physician for testing and medical follow-up.

Confidentiality and the Reporting of Test Results

- *Information ordinarily may not be revealed without the patient's express consent.* Physicians have an obligation to be familiar with federal privacy protection legislation (Health Insurance Portability and Accountability Act) (8). Guidance is provided here for the ethical duty to maintain confidentiality. Maintaining confidentiality is intrinsic to respect for patient autonomy and permits the free exchange of information that is relevant to medical decision making. Situations may arise, however, in which a physician has competing obligations: protecting the patient's confidentiality or disclosing test results to prevent harm to a third party. In these situations, every avenue of communication should be explored first in discussions with the patient about rights and responsibilities. Consultation with an institutional ethics committee or a medical ethics specialist may be helpful in weighing benefits and harms of disclosure. Legal advice may be prudent.
- *A violation of confidentiality may be ethically justified as a last resort.* A violation of confidentiality may be justifiable only when legally required or when all of the following conditions have been met: 1) there is a high probability of harm to a third party, 2) the potential harm is a serious one, 3) the information communicated can be used to prevent harm, and 4) greater good will result from breaking confidentiality than from maintaining it. Case law has not yet been developed to address the grey area where, on rare occasions, legal obligations to protect patient confidentiality and ethical and professional obligations to act for the benefit of the patient may conflict.

Conclusion

In addition to establishing a diagnosis, testing provides opportunities to educate, inform, and advise. The ethical principles of respect for autonomy (patient choice) and beneficence (concern for the patient's best interests) should guide the testing, counseling, and reporting process. Clear and ample communication fosters trust, facilitates access to services, and improves the quality of medical care.

References

1. Beauchamp TL, Childress JF. Priniciples of biomedical ethics. 5th ed. New York (NY): Oxford University Press; 2001.
2. Malm HM. Medical screening and the value of early detection. When unwarranted faith leads to unethical recommendations. Hastings Cent Rep 1999;29:26–37.
3. Offit K, Groeger E, Turner S, Wadsworth EA, Weiser MA. The "duty to warn" a patient's family members about hereditary disease risks. JAMA 2004;292:1469–73.
4. McGowan R. Beyond the disorder: one parent's reflection on genetic counselling. J Med Ethics 1999;25:195–9.
5. Prenatal and perinatal human immunodeficiency virus testing: expanded recommendations. ACOG Committee Opinion No. 304. American College of Obstetricians and Gynecologists. Obstet Gynecol 2004;104:1119–24.
6. Revised recommendations for HIV screening of pregnant women. Centers for Disease Control and Prevention. MMWR Recomm Rep 2001;50(RR-19):63–85; quiz CE1-19a2–CE6-19a2.
7. American Academy of Pediatrics, American College of Obstetricians and Gynecologists. Joint statement on human immunodeficiency virus screening. ACOG Statement of Policy 75. Elk Grove Village (IL): AAP; 2005; Washington, DC: ACOG; 2006.
8. American College of Obstetricians and Gynecologists. HIPAA privacy manual. 2nd ed. Washington, DC: ACOG; 2003.

Patient testing: ethical issues in selection and counseling. ACOG Committee Opinion No. 363. American College of Obstetricians and Gynecologists. Obstet Gynecol 2007;109:1021–3.

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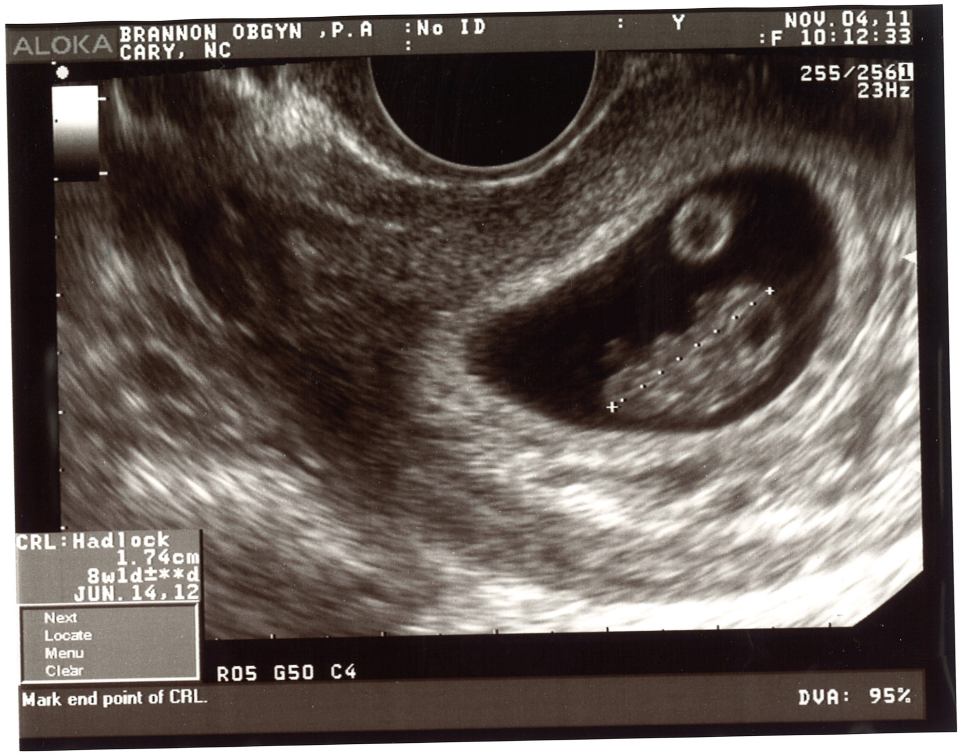
EXHIBIT C:

Ultrasound image of an 8 week 1 day (by Hadlock)
(6 weeks-1 day after fertilization) Unborn Child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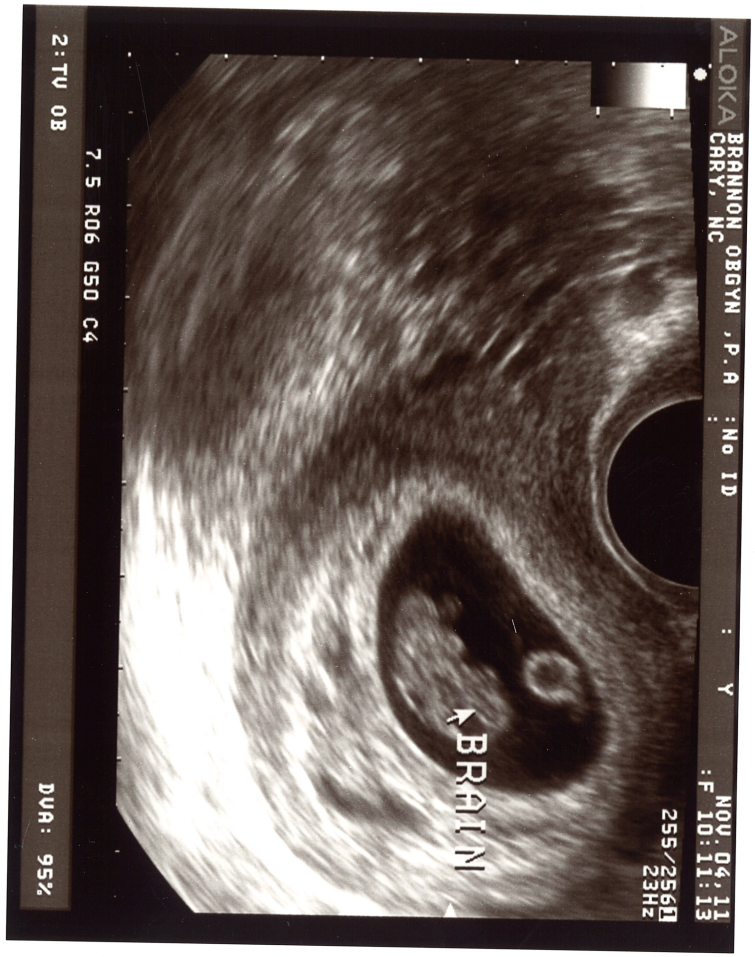
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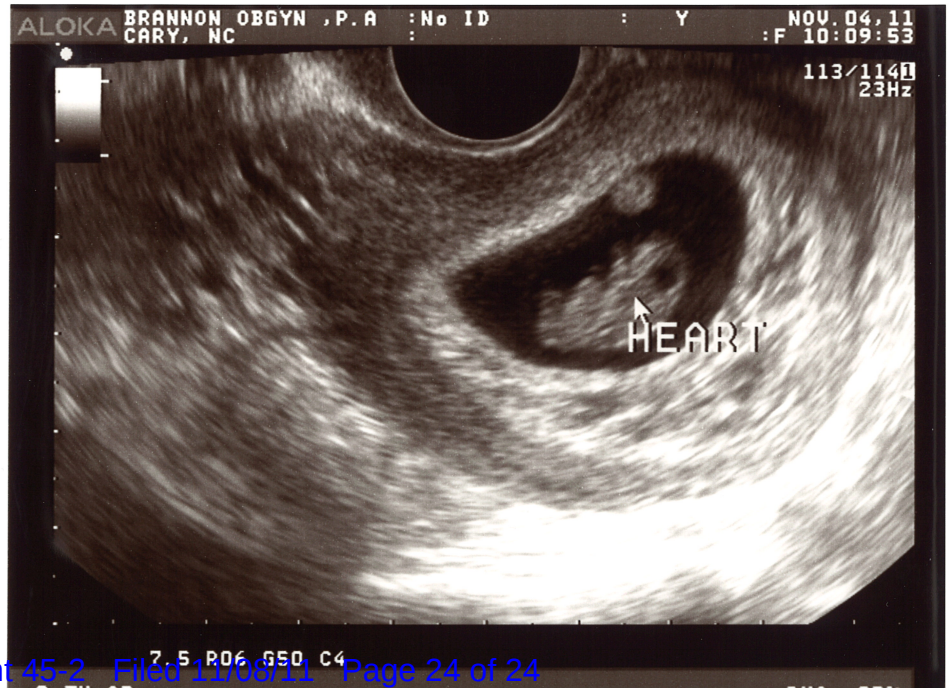
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23Hz
HEART
7.5 R06 G50 C4